

described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to CMS during the probationary period, CMS may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by CMS, does not affect or limit the conducting of any validation survey.

(7) CMS will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After CMS removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. CMS may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to CMS so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to

the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

[58 FR 61841, Nov. 23, 1993]

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[58 FR 61842, Nov. 23, 1993]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation:

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(1) Except those specified in § 488.5;

(2) Provided that such hospital, if it is included within a validation survey, authorizes the JCAHO to release to CMS (on a confidential basis) upon request a copy of the most current JCAHO accreditation survey.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with State survey agencies for the purpose of conducting validation surveys in hospitals accredited by the JCAHO. Section 1865(b) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.

(d) Section 1865(a) of the Act also provides that if CMS finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; critical access hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, CMS may treat the provider or supplier as meeting the conditions.

[53 FR 22859, June 17, 1988, as amended at 56 FR 48879, Sept. 26, 1991; 58 FR 61842, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997]

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of accredited facilities as provided in § 488.7.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

[62 FR 43936, Aug. 18, 1997]

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§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to CMS.

(a) On the basis of these recommendations, CMS will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) An accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the State survey agency.

(b) Notice of CMS's determination will be sent to the provider or supplier.

§ 488.14 Effect of QIO review.

When a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.